

REMARKS

This Response is to the non-final Office Action mailed on April 21, 2009. The Commissioner is hereby authorized to charge any fees that may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. SMDI-5928 (112713-457) on the account statement.

Claims 14 to 38 are pending in the application. Claims 1 to 13 and 39 to 107 were previously withdrawn due to a restriction/election requirement. Claims 23 and 25 have been amended to correct typographical mistakes and should be entered via this Response to final Office Action. No new matter has been added in amending the claims.

The Examiner is thanked for finding potentially allowable subject matter in Claim 22, 30 and 37 if the claims are amended to include their base claim and all intervening claims.

In the Office Action, claims 14 to 16, 19 to 20, 23, 33 to 35 and 38 are rejected under 35 U.S.C. §103(a) as being obvious in view of U.S. 2002/0104800 to Gregory Collins et al. (“*Collins*”) in view of U.S. Pat. No. 4,702,829 to Hans-Dietrich Polaschegg et al. (“*Polaschegg*”). Though claims 29 and 31 are not rejected on page 2 of the Office Action, Applicants note that claims 29 and 31 are discussed in the Office Action. See, Office Action, page 2. Claims 17 to 18 and 24 to 25 are rejected under 35 U.S.C. §103(a) as unpatentable over *Collins* in view of *Polaschegg* and further in view of U.S. Pat. No. 6,830,553 to Jeffrey Burbank et al. (“*Burbank*”). Claims 21, 26, 27 and 32 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Collins* and *Polaschegg* and further in view of U.S. Patent No. 5,932,103 to Rodney Kenley et al (“*Kenley*”). For at least the reasons provided below, Applicants submit that the rejections should be withdrawn.

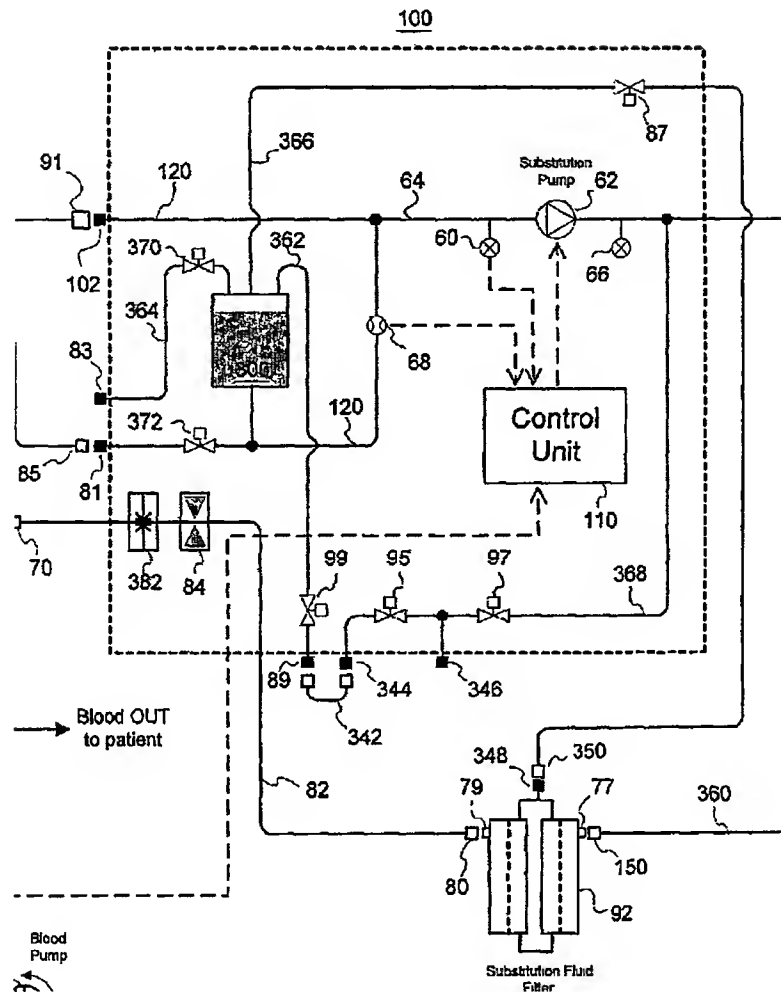
Regarding the obviousness rejection of claims 14 to 16, 19 to 20, 23, 33 to 35 and 38, Applicants submit that primary reference *Collins* fails to disclose or suggest an ultrafilter upstream of the blood filtering device as required, in part, by the present claims. The Office Action admits the same. See, Office Action, page 3. Applicants submit, however, that *Polaschegg* fails to remedy the deficiencies of *Collins*. Even if it would have been obvious to one having ordinary skill in the art to use the ultrafilter of *Polaschegg* as the substitution filter 92 disclosed by *Collins* in order to purify the fluid being sent to the patient, that “ultrafilter” of *Collins* would still not be upstream of the blood filtering device (e.g. dialyzer) as required by the present claims. *Collins* discloses substitution filter 92 as being downstream of substitution pump

62, which functions to separate dialysate from the delivery module 100 (i.e. the dialysate circuit) and draw dialysate through filter 92 to the patient via venous drip chamber 32. See, *Collins*, paragraphs [0039] to [0041] and FIG. 1a. By being part of a separate stream from the dialysate circuit, substitution filter 92 of *Collins* cannot be upstream of the extracorporeal circuit/blood filtering device as required by the claims. Even if *Polaschegg's* ultrafilter replaces *Collins's* substitution filter 92, the resulting "ultrafilter" would still not change the location of *Collins's* substitution filter. Therefore, the "filter" of *Collins* and *Polaschegg* would still not be located as required by the present claims. The combination of *Collins* and *Polaschegg* accordingly still fails to disclose or suggest an ultrafilter upstream of the blood filtering device as required, in part, by the present claims.

Collins further fails to disclose or suggest a flowmeter in fluid communication with a rinse outlet of the ultrafilter as required, in part, by independent claims 14 and 31, and claims 15 to 22 and 32 to 38 that depend claims 14 and 31. As shown in the Applicants' specification, ultrafilter 52 has a rinse outlet 142 connected to a valve 122 and a flowmeter 140 for measuring flow from the ultrafilter. See, specification, paragraph [0094] and Fig. 3. Fresh dialysate enters ultrafilter 52 from input line 48, with purified dialysate leaving through filtration line 88. See, specification, paragraph [0051]. Rinse outlet 142 is provided to remove impurities from the filter and send them to drain 40. See, specification, paragraph [0086] and [0087].

In contrast, *Collins* does not provide any outlet resembling a "rinse outlet" as recited in claims 14 and 31. *Collins* instead provides inlet and outlet ports 77 and 79 of substitution filter 92 and a third filter port 348 for directing dialysate to fluid reservoir 300. A portion of FIG. 1a of *Collins*, shown below, illustrates the three ports connected to filter 92, none of which operate to remove impurities from filter 92 to send to a drain.

FIG. 1a



The Office Action states that *Collins* teaches a flowmeter 68 connected to an outlet of the filter 92 as shown in FIG. 1a. See, Office Action, page 3. As shown in FIG. 1a, however, flowmeter 68 connects to tubing 120 at the inlet/outlet of pump 62 and tank 300. Flowmeter 68 is not connected to any portion of filter 92. In fact, the outlet of filter 92 connects only to pinch valve 84, blood sensor 382, and venous drip chamber 32 of the blood circuit, while flowmeter 68 is connected to the dialysate circuit. Moreover, *Collins* teaches that, for bolus treatment, after

detecting no dialysate flow rate by flowmeter 68, substitution pump 62 is then turned on to divert dialysate to the patient. See, *Collins*, paragraph [0045]. Therefore, *Collins* fails to disclose or suggest a flowmeter in fluid communication with an ultrafilter, let alone in fluid communication with a rinse outlet of an ultrafilter, as required by independent claims 14 and 31.

Regarding dependent claims 19 and 20, which recite a biosensor that may be a hematocrit sensor, a blood volume sensor, an electrolytic sensor, an oxygen sensor, or any combination of these, the Office Action asserts that *Collins* teaches a biosensor, citing paragraphs [0011] and [0045] for a blood flow sensor. Paragraph [0011] of *Collins*, however, teaches the general use of flow meters to control substitution pump speed. Moreover, paragraph [0045] of *Collins* refers to the above-mentioned flow meter 68 as a dialysate flow meter and states that substitution pump 62 may be a metering type pump. Applicants respectfully submit that a flow meter is fundamentally different from a biosensor. A biosensor, for example is defined as a device that is sensitive to a physical or chemical stimulus (as heat or an ion) and transmits information about a life process. Merriam-Webster's Collegiate Dictionary, 10th ed. at 115. The examples in the Markush group of Claim 20 all concern measurements of the blood, which is part of a life process of the patient. A blood volume sensor, for example, is not concerned with blood flow but is used to detect air in the blood, which is very important in the life process of the patient. See, e.g., U.S. Pat. 7,500,962. A general flow sensor for use in a dialysis machine is not a biosensor because it transmits information about the dialysis machine process, not a life process of the patient. The examples from *Collins* therefore teach flow sensors but do not teach or suggest a biosensor as claimed. Accordingly, Applicants respectfully submit that *Collins*' flow sensor does not render obvious the claimed biosensor.

Applicants respectfully submit that *Collins* and *Polaschegg*, alone or in combination, fail to disclose or suggest every element of claims 14 to 16, 19 to 20, 23, 33 to 35 and 38.

Regarding the obviousness rejection of claims 17, 18, 24 and 25 under *Collins* in view of *Polaschegg* and *Burbank*, Applicants respectfully submit that the references do not teach or suggest the elements of these dependent claims. For example, Claim 17 recites, "the control scheme of the claimed medical fluid system is programmed to receive the bolus volume from an entry by an operator when commencing delivery of the bolus volume" (emphasis added). The Office Action asserts that claim 17 is obvious in view of *Collins* and *Burbank*, citing *Burbank*, column 31, lines 27 to 40 as teaching a blood treatment system that automatically sets operating

parameters that can be overridden by an operator. See, Office Action, page 5. Burbank teaches generally that an operator can enter processing objectives and that the machine will set and maintain pump values to achieve these objectives. *Burbank*, column 31, lines 27 to 30. *Collins* teaches in paragraph [0045] that the bolus volume is controlled by pumping a certain number of strokes or by visually monitoring the amount of fluid and the level changes in fluid reservoir 300. These disclosures are clearly at odds with claim 17 because counting the strokes (or even entering the number of strokes) or visually observing the level in the reservoir is not equivalent to a claimed control scheme programmed to receive the bolus volume “from an entry by an operator when commencing delivery of the bolus volume.”

Applicants respectfully submit therefore that the cited references, alone or in combination, fail to disclose or suggest every element of claims 17, 18, 24 and 25.

Regarding the obviousness rejection of claims 21, 26, 27 and 32, Applicants respectfully submit that *Kenley* fails to remedy the deficiencies of *Collins* and *Polaschegg* discussed above in regards to independent claims 14, 23 and 31. Instead of citing *Kenley* as evidence of elements of the independent claims, the Office Action relies on *Kenley* arguably to teach elements of dependent claims 21, 26, 27 and 32, namely a dialysis system that allows for post-dilution and for use of dialysis fluid as rinseback communicated to patient post-therapy upon patient input. See, Office Action, page 6.

Applicants respectfully submit therefore that the cited references, alone or in combination, fail to disclose or suggest every element of claims 21, 26, 27 and 32.

Accordingly, Applicants respectfully request that the obviousness rejections of claims 14 to 38 be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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